# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

MINNEAPOLIS FIREFIGHTERS' RELIEF ASSOCIATION, et al.,

Civil No. 0:08-cv-06324-PAM-AJB

Plaintiffs,

v.

MEDTRONIC, INC., et al.,

Defendants.

# PLAINTIFFS' SECOND SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS DIRECTED TO DEFENDANTS MEDTRONIC, INC., ARTHUR D. COLLINS, WILLIAM A. HAWKINS AND GARY L. ELLIS

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Lead Plaintiffs, by their attorneys, hereby request that defendants Medtronic, Inc., Arthur D. Collins, William A. Hawkins and Gary L. Ellis (collectively, "Defendants") each separately produce and permit Lead Plaintiffs' counsel to inspect and copy those documents hereinafter specified, which are in the possession, custody or control of Defendants, in accordance with the Definitions and Instructions set forth below, at the offices of Chestnut Cambronne, 17 Washington Avenue North, Suite 300, Minneapolis, Minnesota 55401-2048, within thirty (30) days after service of these requests.

#### I. <u>DEFINITIONS</u>

- 1. "Board Meeting" means any meeting of the Board, whether conducted face-to-face, telephonically, or by means of other Electronic Media, including all regular Board meetings, all special Board meetings, and all meetings of any committees or subcommittees of the Board.
- 2. "Board of Directors" or "Board" means the Board of Directors of Medtronic and any member or committee thereof.
  - 3. "Class Period" means November 20, 2006 through November 17, 2008, inclusive.
- 4. "Communication" and "communications" mean a transmission or receipt of information of any kind through any means, or any document embodying the transmission or receipt of information.
- 5. "Complaint" means the Consolidated Class Action Complaint filed in the abovecaptioned action on August 21, 2009.
- 6. "Corporate Integrity Agreement" means the agreement entered into by Medtronic and the U.S. Department of Health & Human Services, Office of Inspector General on July 14, 2006.
- 7. "Correspondence" means any letter, memorandum, note, text message, instant message, e-mail or other writing or document transmitted by any means between or among persons or entities.
- 8. "Document" or "documents" means anything that may be considered to be a document or tangible thing within the meaning of Rule 34 of the Federal Rules of Civil Procedure, and includes any writing, report, memorandum, file, communication, transmission of Electronically Stored Information ("ESI") through Electronic Media, correspondence, study, minutes, bulletin, instruction, literature, notes, notebook, diary, data sheet, work sheet, recording,

drawing, graph, index, chart, telephone record, photograph or other graphic matter, including any drafts of the foregoing items and any copy or reproduction of any of the foregoing items upon which any notation, work, figure, or form is recorded or has been made which does not appear on the original or as to whose existence, either past or present, the responding party has any knowledge or information. These terms are intended to have the broadest possible meaning under Rule 34 of the Federal Rules of Civil Procedure.

- 9. "Electronic Media" means any magnetic, optical or other storage media device used to record ESI. Electronic Media devices may include computer memories, hard disks, floppy disks, hard drives, memory sticks, CDs, CD-ROMs, DVDs, personal digital assistance devices (e.g., Palm, Blackberry, iPhone or other "smart phones"), magnetic tapes of all types or any other means for digital data storage and/or transmittal.
- 10. "Employee" or "employees" means any person who at any time during the period covered by this demand (whether the person is a current or former employee) acted or purported to act on behalf of Medtronic, including all past and present directors, officers, executives, agents, representatives, attorneys, accountants, independent contractors, advisors, analysts and consultants (whether paid or unpaid).
- 11. "Engagement" means the engagement or retention of a consultant or other third party of any nature, including the engagement or retention of physicians, surgeons or other medical professionals or facilities to provide academic research and study, promotion and marketing activities, or to conduct or otherwise participate in seminars, lessons, discussions, meetings or presentations, whether formal or informal, with respect to medical devices designed, marketed and/or sold by Medtronic.
  - 12. "ESI" means any original and any non-identical copies resulting from the use of

any software program (e.g., word processing documents, spreadsheets, worksheets, database files, charts, graphs and outlines), electronic mail ("e-mail"), PDF files or ASCII files, regardless of the Electronic Media on which they reside and regardless of whether the ESI consists of an active file, backup file, deleted file or file fragment. ESI also includes, without limitation, any items stored on Electronic Media in files, folder tabs, or containers and labels appended to or associated with any physical storage device associated with each original and each copy.

- 13. "Executive Committee" means the Executive Committee of Medtronic and any member or committee thereof.
- 14. "FDA" refers to the United States Food and Drug Administration and any subdivision thereof, person, employee, agent, or representative acting on its behalf.
- 15. "Individual Defendants" means Arthur D. Collins, William A. Hawkins and Gary L. Ellis.
- 16. "INFUSE" means any medical device containing the genetically engineered protein rhBMP-2, including the INFUSE® BONE GRAFT/LT-CAGE® Lumbar Tapered Fusion Device which consists of two components, the INFUSE Bone Graft, that includes an absorbable collagen sponge ("ACS") with rhBMP-2 and the LT CAGE® Lumbar Tapered Fusion Device.
- 17. "Key Opinion Leaders" means physicians, surgeons or any other medical professionals compensated by Medtronic in any manner to present, promote or market INFUSE, including as described in ¶92-93 of the Complaint.
- 18. "LT CAGE" means LT CAGE® Lumbar Tapered Fusion Device, a component of INFUSE.
- 19. "Medtronic" means Medtronic, Inc. and shall have the same meaning as defined in the Complaint, and any of its parents, subsidiaries, divisions, subdivisions, affiliates,

predecessors, successors, assigns, officers, directors, boards of directors or committees thereof, present or former employees, representatives or agents (including, without limitation, their attorneys, accountants and advisors), and all other persons occupying similar positions or performing similar functions or acting, purporting to act or authorized to act on its behalf.

- 20. "Meeting," "meet," and "met" refer to any assembly, convocation, encounter or contemporaneous presence of two or more persons for any purpose, whether or not planned, arranged or scheduled in advance, during which a communication of any kind occurred, and includes formal and informal gatherings, conversations, video or WebEx conferences and telephone calls.
- 21. "Person" means natural persons, proprietorships, governmental agencies, corporations, partnerships, trusts, joint ventures, groups, associations, organizations, and all other entities.
- 22. "Policy" or "policies" means any rule, procedure, practice or course of conduct, whether formal or informal, written or unwritten, recorded or unrecorded, that was recognized or followed on either a regular or irregular basis, explicitly or implicitly, in whole or in part, by any Defendant responding to these requests.
- 23. "Relating to" or "referring to" means referencing, constituting, representing, defining, depicting, concerning, embodying, identifying, stating, mentioning, addressing or pertaining to in any way. A document, communication or correspondence "relating to" or that "relate(s) to" a given subject matter concerns, constitutes, contains, embodies, comprises, demonstrates, expresses, evidences, reflects, identifies, mentions, states, shows, refers to, deals with, comments on, responds to, describes or analyzes that subject, including documents, communications, or correspondence concerning the contents of other documents,

communications or correspondence.

- 24. "Report" means communications to, between or among supervisory, executive or managerial persons and entities (e.g., boards, committees and subcommittees thereof), whether such communications are formal or informal, regular or periodic, permitted, required or prohibited, public or confidential, official or unofficial.
  - 25. "rhBMP-2" refers to recombinant human bone morphogenetic protein-2.
- 26. "Securities" include notes, bonds, options, warrants, calls, puts, common or preferred stock, debentures or evidence of indebtedness.
- 27. "Securities analysts" means any investment analyst, securities dealers, securities brokers, investment bankers, registered representatives, and any officers, directors, agents or employees thereof.
- 28. "You" and "your" mean collectively Medtronic, Arthur D. Collins, William A. Hawkins and Gary L. Ellis.

#### II. RULES OF CONSTRUCTION

- 1. The following rules of construction shall apply to all definitions, instructions and discovery requests herein:
  - a. The words "all" and "any" mean "any and all;"
  - b. The term "including" means "including, but not limited to;"
  - c. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the definition, instruction or request all information that might otherwise be construed to be outside of its scope;
  - d. The use of the singular form of any word includes the plural and vice versa; and

e. The use of any tense of any verb shall also include within its meaning all other tenses of that verb.

## III. <u>INSTRUCTIONS</u>

- 1. You are requested to produce all documents not subject to a valid objection that are known by, possessed by, controlled by, or available to you. This duty is not limited or affected by the fact that the same document is available through another source. Your responses shall specify which Defendant has or had custody, possession or control of the documents produced.
- 2. These document requests are continuing so as to require supplemental responses, as specified in Rule 26(e) of the Federal Rules of Civil Procedure.
- 3. Pursuant to Rule 34(b) of the Federal Rules of Civil Procedure, documents shall be produced as they are kept in the usual course of business or the documents shall be organized and labeled to correspond to the categories in these requests. In the case of documents that were already produced pursuant to federal, state or local government or administrative requests, investigations or subpoenas, those documents should be produced in the same manner as they were previously produced by you, provided that the manner in which these documents were produced corresponds with the manner requested herein.
- 4. Documents shall be produced in such fashion as to identify the department, branch or office in whose possession it was located and, where applicable, the natural person in whose possession it was found and the business address of each document's custodian(s).
- 5. You are required to produce the original of each document requested together with all non-identical copies and drafts of each document. If the original of any document cannot be located and/or produced, provide a copy in lieu thereof, which shall be legible and bound or stapled in the same manner as the original, and produce all other non-identical copies

that differ from the original and from the other copies produced for any reason, including without limitation, the making of notes thereon.

- 6. Documents attached to each other in their original form should not be separated when produced. Any attachments to e-mail messages should be produced with, and linked to, the attaching e-mail.
- 7. The scope of your search for documents, ESI or Electronic Media that is responsive to any request shall include all forms of electronic data collection, preservation, transmission, communication and storage, including but not limited to:
  - All ESI generated and maintained in the ordinary course of business, including ESI stored on mainframe computers or local stand-alone and networked computers, servers or others;
  - b. Distributed data or removable data, *i.e.*, information which resides on portable media and non-local devices, including home computers, laptop computers, magnetic or floppy discs, CDs, DVDs, zip drives, Internet repositories of all types, including web-sites, e-mail hosted by Internet service providers ("ISP"), handheld storage devices such as PDAs, cellular telephones, and flash memory drives;
  - Forensic copy or backup data, including archive and backup data tapes and discs;
  - Network data, including voice mail systems, e-mail servers, ISP servers, instant messaging servers, network servers, and fax servers;
  - e. Legacy data, *i.e.*, retained data that has been created or stored by the use of software or hardware that has been rendered outmoded or obsolete;

- f. Metadata, *i.e.*, information regarding a particular data set which describes how, when and by whom it was collected, created, accessed, printed and/or modified and how it is formatted or used; and
- g. Residual or deleted data, *i.e.*, data that is not active on a computer system, including data found on media free space, data found on media slack space and data within files that have been functionally deleted.
- 8. If you have reason to believe there are responsive e-mails created during this period that have not been retained, state the name and address of the e-mail services or ISP (e.g., intra-company, Bloomberg, Gmail, Yahoo! or AOL) used by Defendants or any employee of Medtronic during the period and what efforts you have made to retrieve the requested information.
- 9. If any of the Individual Defendants created, made entries in, employed or maintained at home or while traveling any notebooks, diaries, schedules, phone logs and e-mails, in print or in electronic format (such as on laptop computers, PDAs, flash memory drives or other similar devices), concerning or referencing any of the above-described documents or ESI, these are to be produced.
- 10. ESI produced pursuant to these requests shall be produced in tagged image file format or "TIFF" images, without alteration or modification. Where such ESI consists of emails, spreadsheets, audio or video files or Microsoft PowerPoint presentations, or any other file type that cannot be produced as usable TIFF images, such ESI shall also be produced in their "native" or original electronic format, without alteration or modification. Where such electronic data has been encrypted or otherwise protected from third party access, you should, to the fullest extent possible, de-crypt or unlock such files or data to allow access by third parties. In addition

to producing the above-referenced ESI in native format, to the extent that you have any specialized software that will allow any ESI to be translated into usable form, such translated data should be produced as well.

- 11. ESI produced pursuant to this request shall be produced in searchable format with a standard load file (to be mutually agreed upon) and an accompanying index that states the following Metadata:
  - a. DocID the electronically stored identification number assigned to the document;
  - b. PgCount the number of pages of the document;
  - c. Beg doc# document's first Bates number;
  - d. End doc# document's last Bates number;
  - e. Secondary begin doc# first Bates number of unit (first page of any attachments to documents or attachments to attachments);
  - f. Secondary end doc# ending Bates number of unit (last page of last attachment to documents);
  - g. Owner or Custodian name of person whose files the document comes from;
  - h. DocDate date of file;
  - i. Timesent the time the file was sent;
  - j. Filesize number of bytes in the file;
  - k. File name name of the file;
  - 1. Document Type Document type;
  - m. Doc Title re: line of Document;
  - n. Author the author of the Document;

- o. From the person who sent and/or authored the Document;
- p. Recipient the person(s) who were sent and/or received the Document;
- q. To the person(s) who were sent and/or received the Document;
- r. cc-copies;
- s. bcc blind copies;
- t. Text;
- u. Creation date;
- v. Modification Date; and
- w. Path/File name.
- 12. E-mail (together with any attachments) shall be produced with the following fields combined in an index of Metadata:
  - a. Owner or Custodian name of person whose e-mail file or other e-files
     are being provided;
  - b. File Name name of file;
  - c. File Date date of file;
  - d. File Size size of file;
  - e. Extracted-Text; and
  - f. Parent/Child relationship (i.e., identifying electronic documents attached to e-mail by corresponding Bates number).
- 13. Paper-based documents produced pursuant to these requests should be scanned and produced as single-page TIFF images, with corresponding optical character recognition or "OCR" in matching fields [single image = single page of text], and all corresponding ancillary data, to the extent such information exists. When producing scanned images, the custodian

whose paper documents are scanned should be identified, as well as the file drawer, box or file-folder information, as available, from where the documents were stored and/or found. In the event that the party assembling such documents creates an index of objective, bibliographical information from those documents, that index, list or information otherwise assembled, is to be produced together with the scanned images. Also, attachment ranges should be identified either by appropriately numbered ranges or by some cross-reference list (to be mutually agreed upon).

- 14. If you are unable to respond fully to any document request, respond to the extent possible, and specify the reasons for your inability to respond in full and describe to the best of your knowledge, information and belief, and with as much particularity as possible, those portions of the document that are not being produced.
- 15. When an objection is made to any request, the objection shall state with specificity all corresponding grounds. Any ground not stated in an objection within the time provided by the Federal Rules of Civil Procedure and the Local Rules for the United States District Court for the District of Minnesota, or any extensions thereof, shall be deemed to have been waived.
- 16. If any document is withheld, in whole or in part, for any reason, including, but not limited to, any claim of privilege, whether work-product or attorney-client, confidentiality or trade-secret, you shall provide a privilege log setting forth separately with respect to each such document: (a) the nature of the privilege or ground of confidentiality claimed; (b) the type of document; (c) the authors of the document; (d) the addressees of the document; (e) all persons who received copies of the document; (f) the date of the document; (g) the general subject matter of the document; and (h) the Bates and/or control number(s) assigned to the document.
  - 17. If a document contains both privileged and non-privileged material, the non-

privileged material must be disclosed to the fullest extent possible without thereby disclosing the privileged material. If a privilege is asserted with regard to part of the material contained in a document, you must clearly indicate the portions as to which the privilege is claimed in accordance with the procedure outlined above.

- 18. If a document responsive to these requests was at any time in your possession, custody or control, but is no longer available for production, state as to each such document the following information:
  - a. Whether the document is missing or lost;
  - b. Whether the document has been destroyed;
  - Whether the document has been transferred or delivered to another person or entity and, if so, to whom and at whose request;
  - d. Whether the document has been otherwise disposed of; and
  - e. A precise statement of the circumstances surrounding the disposition of the document and the date of its disposition.
- 19. Documents not otherwise responsive to these requests shall be produced if such documents mention, discuss, refer to, or explain the documents that are called for by these requests, or if such documents are attached to documents called for by the requests and constitute routing slips, transmittal memoranda or letters, comments, evaluations or similar materials.

## IV. DOCUMENT REQUESTS

- 1. All documents relating to the marketing, sales or promotion of the INFUSE MasterGraft Posterolateral Revision Device pursuant to the FDA Humanitarian Device Exemption ("HDE"), including any discussion of the use of the HDE to market INFUSE.
- 2. All communications and documents exchanged between Medtronic and any third party education, consulting, auditing or marketing firm relating to INFUSE.

- 3. Documents sufficient to identify all payments made by Medtronic to any third party education, consulting, auditing or marketing firm for work performed relating to INFUSE.
  - 4. All WebEx meeting transcripts relating to the promotion and use of INFUSE.
- 5. All communications between Medtronic and its outside auditors relating to auditor queries concerning payments made by Medtronic to any third party entity or individual regarding INFUSE.
- 6. All documents relating to "Bill Hawkins' December 2005 Memorandum on Unapproved Uses Policy," including the memorandum itself (referenced in MDTFF-E00017300).
- 7. All documents relating to "8 Legal Guidances on Unapproved Uses January 31, 2008," including the memorandum itself (referenced in MDTFF-E00017300).
- 8. All documents relating to each "Biologics Quarterly Plan Review," "DSM Quarterly Plan Review" and "DSR Quarterly Plan Review" for all Medtronic employees whose job responsibilities included INFUSE.
- 9. All documents provided to or considered, discussed or prepared by or on behalf of Medtronic's Executive Committee and subdivisions or committees thereof relating to INFUSE.
- 10. All documents regarding the Executive Compliance Committee and/or Ethics Compliance Committee and/or Audit Committee relating to INFUSE and the Corporate Integrity Agreement, including communications, meeting minutes, presentations and reports prepared for or on behalf of these committees.
- 11. All documents exchanged between Medtronic and Corpedia Corporation or any other third party firm that Medtronic considered retaining, or did retain, to assist in the implementation of and compliance with the Corporate Integrity Agreement.

- 12. All documents relating to the drafting, negotiation or execution of the January 1, 2004 Personal Services Agreement between SDGI Holdings, Inc. and Scott Boden ("2004 Boden Agreement"), including any discussion or analysis as to the characterization of payments or other compensation under said agreement and the services that Boden would provide to Medtronic pursuant to the 2004 Boden Agreement.
- 13. All documents relating to the drafting, negotiation or execution of the January 1, 2005 Product Development, Purchase and Royalty Agreement between SDGI Holdings, Inc. and Scott Boden ("2005 Boden Agreement"), including any discussion or analysis as to the characterization of payments or other compensation under said agreement and the services that Boden would provide to Medtronic pursuant to the 2005 Boden Agreement.
- 14. All documents relating to the drafting, negotiation or execution of the February 28, 2006 Product Development, Purchase and Royalty Agreement between SDGI Holdings, Inc. and Scott Boden ("2006 Boden Agreement"), including any discussion or analysis as to the characterization of payments or other compensation under said agreement and the services that Boden would provide to Medtronic pursuant to the 2006 Boden Agreement.
- 15. All documents relating to the drafting, negotiation and execution of any buyout of the 2006 Boden Agreement, including any discussion or analysis about the characterization of payments or other compensation under the 2006 Boden agreement.
- 16. All documents relating to Medtronic's engagement of Independent Review Organization(s) under §III.E.1 of the Corporate Integrity Agreement.
- 17. All documents relating to the Implementation Report under §V.A of the Corporate Integrity Agreement.
  - 18. All documents relating to the Annual Report(s) under §V.B of the Corporate

# Integrity Agreement.

- 19. All documents relating to reports generated by external auditors for Medtronic regarding INFUSE, Key Opinion Leaders and the Corporate Integrity Agreement.
- 20. All documents relating to fluctuations in the Company's stock price, including internal discussions regarding the reasons for stock price increases or declines (or the lack thereof), market reaction to news regarding Medtronic, its competitors or the overall market, and communications with investors, securities analysts or third parties regarding the Company's stock price.
- 21. All documents relating to Medtronic's investor relations and/or public relations departments, including internal communications, memos, notes or scripts regarding the Company's response to positive/negative announcements or news, and any communications with the media, securities analysts, rating agencies or investors regarding the Company or its stock price.
- 22. All documents relating to the September 4, 2008 *The Wall Street Journal* article entitled "Medtronic Product Linked to Surgery Problems" referenced in ¶254 of the Complaint, including any internal or external communications regarding same.
- 23. All documents relating to the September 4, 2008 report published by UBS entitled "INFUSE Risks Real, but Largely Known," including any internal or external communications regarding same.
- 24. All documents relating to the September 5, 2008 article published in the *St. Paul Pioneer Press* entitled "FDA Warns About Use of Medtronic Bone Protein," including any internal or external communications regarding same.
  - 25. All documents relating to the October 2, 2008 report published by Thomas Weisel

Partners entitled "Medtronic, Inc.," including any internal or external communications regarding same.

- 26. All documents relating to the November 12, 2008 publication of the JP Morgan survey entitled "Medtronic," including any internal and external communications regarding same.
- 27. All documents relating to the Medtronic Business Conduct Standards Violations and Disciplinary Policy that went into effect in April 2005, including reports of all violations of said policy relating to INFUSE.
- 28. All documents relating to the November 14, 2008 William Blair and Company analyst report referenced in ¶261 of the Complaint, including any internal or external communications regarding same.
  - 29. All documents relating to Medtronic's "Spinal CIA Dashboard."
- 30. All documents relating to, or reports derived from, Medtronic's J: Drive created for its sales force, including information on physicians, prescribing habits with respect to INFUSE and similar spine treatments, and internal comments about said physicians and the results of sales representative visits.
  - 31. All documents relating to Medtronic's "Operation Collaboration."
- 32. All documents relating to any document preservation instructions or litigation holds placed on the contents of Medtronic's J: drive.
  - 33. All documents reflecting the content of http://www.myspinetools.com/?v=1.
- 34. All reports relating to PRs associated with INFUSE, apart from CAM06021. This includes all reports relating to PR 1606, PR 4335 and PR 1610.
  - 35. All documents relating to INFUSE that were distributed at medical conferences

where Medtronic or its representatives presented.

- 36. All documents relating to INFUSE that were distributed at VIP meetings and presentations.
  - 37. All documents comparing INFUSE to Stryker Corporation OP-1 Putty.
- 38. All documents relating to INFUSE that were distributed or referenced at national sales meetings, including all documents relating to "break out sessions" and all documents referenced in MDTFF-E00427184.
  - 39. All documents relating to the INFUSE launch referenced in MDTFF-E01040142.
- 40. All documents relating to Medtronic's obsolete literature regarding INFUSE (referenced in MDTFF-E01925868), including all policies and procedures relating to obsolete documents, a copy of all documents destroyed and all documents relating to the October 2007 FDA Warning Letter.
- 41. All minutes of Medtronic Biologics Office of Medical Affairs meetings, including all documents distributed or considered during the meetings.
- 42. All documents relating to any approval or non-approval of any request under the procedures set forth in the "Work Instruction, Affirmative Dissemination of Information about Unapproved Uses of MSD Products (Document No. PL001)" produced at MDTFF-E0023309, including the "References" cited on MDTFF-E00233099, and any cover letters, communications, disseminated documents, and written approval documents cited in Sections 5.0 and 6.0 of Document No. PL001.

DATED: May 16, 2011

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